Obesity Surgery (2021) 31:3427–3433
https://doi.org/10.1007/s11695-021-05437-3

ORIGINAL CONTRIBUTIONS

Long-term Effects of Laparoscopic Sleeve Gastrectomy: What Are the Results Beyond 10 Years?

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Received: 10 March 2021 / Revised: 8 April 2021 / Accepted: 13 April 2021 / Published online: 22 April 2021

Abstract

Purpose Laparoscopic sleeve gastrectomy (LSG) has become the most commonly performed bariatric procedure worldwide. Newer studies providing long-term follow-up show a high incidence of weight regain and a high incidence of reflux. The study's objective was to present 5 to 15-year follow-up results regarding weight loss, comorbidities, reoperation rate, and a potential learning curve.

Methods This is a retrospective analysis of prospectively collected data. Patients who underwent LSG between August 2004 and December 2014 were included.

Results A total of 307 patients underwent LSG either as a primary bariatric procedure ($n = 262$) or as a redo operation after failed laparoscopic gastric banding ($n = 45$). Mean body mass index at the time of primary LSG was 46.4 ± 8.0 kg/m^2, and mean age at operation was 43.7 ± 12.4 years with 68% females. Follow-up was 84% and 70% at 5 and 10 years, respectively. The mean percentage excess body mass index loss (%EBMIL) for primary LSG was 62.8 ± 23.1% after 5 years, 53.6 ± 24.6% after 10 years, and 51.2 ± 20.3% after 13 years. Comorbidities improved considerably (e.g., type 2 diabetes mellitus 61%), while the incidence of new-onset reflux was 32.4%. Reoperation after LSG was necessary in almost every fifth LSG-patient: 24 patients (7.8%) were reoperated due to insufficient weight loss, 12 patients (3.9%) due to reflux, 23 due to both (7.5%).

Conclusions LSG provides a long-term %EBMIL from 51 to 54% beyond 10 years and a significant improvement of comorbidities. On the other hand, a high incidence of insufficient weight loss and de novo reflux was observed, leading to reoperation and conversion to a different anatomy in 19.2%.

Keywords Sleeve gastrectomy · Long-term results · Weight loss · Reflux · Learning curve

Marko Kraljević and Vanessa Cordasco contributed equally to this work.

Keypoints
A retrospective study of 307 obese patients who underwent LSG as a primary or revisional procedure
LSG provides a mean %EBMIL from 51 to 54% beyond 10 years and a significant improvement of comorbidities.
The incidence of de novo reflux after LSG was 32.4% in the long-term.
Reoperation and conversion from LSG to different anatomy was necessary in almost every fifth patients.

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Introduction

Obesity and its related comorbidities are still increasing worldwide [1]. Bariatric surgery is the most effective treatment for morbid obesity, as it leads to adequate long-term weight loss and a significant reduction of obesity-related comorbidities and mortality [2]. Procedures have significantly changed during the last 30 years: In Europe, laparoscopic adjustable gastric banding (LAGB) was the number 1 procedure during the 1990s and was increasingly being replaced by laparoscopic Roux-en-Y gastric bypass (LRYGB). Initially, laparoscopic sleeve gastrectomy (LSG) was described as the first step of biliopancreatic diversion duodenal switch (BPD/DS) [3] or primary intervention in high-risk patients before LRYGB [4]. Meanwhile, LSG gained popularity as a standalone operation due to its laparoscopic feasibility and short learning curve and has now become the most commonly performed bariatric procedure worldwide [5]. Short-term and mid-term results have been published with promising data regarding its safety and effectiveness [6, 7]. However, newer studies providing long-term follow-up are showing a high incidence of weight regain [8, 9]. Recent studies also showed a high incidence of de novo reflux or worsening of preexisting gastroesophageal reflux disease (GERD) after LSG leading to conversion to a different bariatric procedure [10, 11]. Some authors also reported de novo development of Barrett's esophagus after LSG due to chronic acid exposure [11, 12]. However, all bariatric operations have a certain number of non-responders regarding weight loss or complications. To evaluate the long-term safety and effectiveness of LSG, more long-term results are needed. Our present study aimed to evaluate the long-term results of LSG in terms of weight loss, remission of comorbidities, and complication and reoperation rate at a single institution with a minimal follow-up time of 5 years, and in addition to define the length of a potential learning curve.

Methods

Design and Subjects

Patients' data were obtained from a prospectively collected database containing all patients that underwent LSG at our institution, either as primary intervention (pLSG) or as a redo LSG after LAGB (rLSG). Our overall rate for primary bariatric procedures is 20% for LSG and 80% for LRYGB. However, the current rate is in favor of LRYGB (85%) due to the better long-term results in terms of weight loss and resolution of comorbidities compared to LSG [7, 13]. All patients who underwent LSG surgery between August 2004 and December 2014 were included. The local ethics committee approved the study. Criteria for bariatric surgery were initial body mass index (BMI) of 35 kg/m^2 in combination with or without obesity-related comorbidities, age between 18 and 65 years, and failure of conservative treatment over 2 years according to guidelines of the Swiss Society for the Study of Morbid Obesity and Metabolic Disorders (www.smob.ch). Zacharoulis et al. described the learning curve to be around the 68th case [14]. Therefore, patients with pLSG were divided into two groups depending on the time of operation (group 1: August 2004 to December 2011, group 2: January 2012 to December 2014) to examine the impact of the learning curve of two bariatric surgeons.

Surgical Technique

All patients were operated on using a standardized operation technique varying very little over time, which was performed by an experienced bariatric team. For LSG, we used a 35 French bougie along the lesser curvature for calibration of the gastric tube; the longitudinal resection of the stomach was done from approximately 4 to 6 cm orally of the pylorus towards the angle of His. The staple line was routinely oversewn with an absorbable running suture. All patients scheduled for LSG underwent gastroscopy, upper gastrointestinal series, and esophageal manometry; in addition, the hiatus was explored intraoperatively. Large hiatal hernias or severe motility disorders were contraindications for LSG. If a smaller hiatal hernia was present, cardia was explored, repositioned, and repaired with posterior closure of the crura.

Follow-up

All patients were followed up on an outpatient basis regularly over the entire study period. The follow-up consisted of careful documentation of weight changes, history of revisional surgery, and quality of life assessments. If sufficient weight loss could not be achieved by LSG, there was a possibility of increasing the bariatric treatment to a laparoscopic BPD/DS. However, this procedure was only offered to compliant patients in terms of vitamin supplementation, protein intake, and good adherence to follow-up in the outpatient clinic. For this purpose, patients were reevaluated by the interdisciplinary team (dietitian, endocrinologist, psychiatrist, and surgeon). In case of severe gastroesophageal reflux unresponsive to medical treatment, a conversion to LRYGB was considered. Insufficient weight loss was defined either by EBMIL below 25%, and/or by lack of remission, recurrence, and respectively new onset of comorbidities.

Outcome Measures

Outcome measures included details of the index and the revisional bariatric procedure (if available), early and late complications, changes in weight, BMI, and comorbidities.

Weight outcomes were recorded as follows: mean initial BMI, %TWL defined as [(initial weight)−(postoperative weight)] / (initial weight) × 100 and %EBMIL defined as [(initial BMI)−(postoperative BMI)] / [(initial BMI)−(ideal BMI)]. Ideal BMI was defined as a BMI of 25 kg/m^2. Comorbidities evaluated preoperatively and postoperatively included T2DM, arterial hypertension, abnormal lipid profile, and GERD.

Definitions of comorbidities were arterial hypertension (systolic blood pressure > 140 mmHg, diastolic blood pressure > 90 mmHg with/without the use of antihypertensive medication), T2DM (HbA1c > 6.5% with/without the use of antidiabetic medication), hyperlipidemia (elevated cholesterol and/or triglycerides), and GERD (esophagitis ≥ grade B according to the Los Angeles classification). The preexisting medical treatment, mainly antidiabetic and antihypertensive drugs, was adjusted to the current need.

The postoperative course of comorbidities was defined as follows: remission: no symptoms/without any medication; remission of T2DM was defined according to the American Diabetes Association criteria: complete remission: HbA1c < 6.0%, fasting glucose < 100 mg/dl, and at least 1 year no active pharmacologic therapy; partial remission HbA1c < 6.5% [15], improvement: fewer symptoms and/or less medical treatment/medication; unchanged: same symptoms and equivalent therapy; and worsened: more symptoms or increase of therapy. De novo comorbidity: comorbidity is not present at baseline but newly developed within the postoperative course.

Statistical Analysis

All data are presented as mean values ± standard deviation or median with 95% confidence interval (CI), as applicable. For continuous data, the Student's *t*-test and the Mann Whitney *U* test were used, as appropriate. Comparison of categorical data was performed with the chi-squared test. Statistical significance was defined by $p < 0.05$. All statistical analyses were performed using SPSS Statistics, Version 23.0.0.0.

Table 1 Patients' characteristics in primary (pLSG) and revisional laparoscopic sleeve gastrectomy (rLSG, secondary procedure after gastric banding). Data are given as mean ± SD. *pLSG*, primary laparoscopic sleeve gastrectomy; rLSG, revisional laparoscopic sleeve gastrectomy; BMI, body mass index

	pLSG	rLSG	p value
n	262	45	NA
Female (%)	67.9	79.9	0.116
Age (years)	43.7 ± 12.4	41.6 ± 8.8	0.276
Initial weight (kg)	132.1 ± 27.1	131.1 ± 26.2	0.800
Initial BMI (kg/m^2)	46.4 ± 8.0	46.3 ± 6.0	0.936
Prerevisional BMI (kg/m^2)	NA	39.7 ± 7.3	NA
Excess weight (kg)	60.9 ± 23.6	60.7 ± 20.7	0.957
Excess BMI (kg/m^2)	21.4 ± 8.0	21.3 ± 6.0	0.936

Results

Patient Characteristics

A total of 307 patients underwent LSG either as pLSG bariatric procedure ($n = 262$) or as rLSG operation after laparoscopic gastric banding ($n = 45$). Table 1 demonstrates the preoperative demographics of all patients. Reasons to convert from gastric banding to LSG were band intolerance in 19 patients (38.8%), slippage in 12 (24.5%), insufficient weight loss in 11 (22.4%), concentric pouch dilation in four (8.2%), and acute food intolerance (the inability to eat solid food and relief after band opening) in three patients (6.1%). Multiple reasons for conversion were possible. Baseline demographic characteristics were similar in both groups, except that slightly more females were included in group 1 (Table 2). The mean follow-up time was 7.5 ± 3.4 years. Follow-up rates were 84.0% at 5 years and 69.6% at 10 years, 67.1% at 11 years, 61.8% at 12 years, and 60.4% at 13 years. Dropout reasons were loss to follow-up ($n = 74$), change of residence ($n = 8$), or death ($n = 8$, reasons see below). The presence of comorbidities at baseline in all patients was as follows: T2DM in 77/307 patients (25.1%), hypertension in 167/307 patients (54.4%), hyperlipidemia in 179/307 patients (58.3%), and sleep apnea in 62/307 patients (23.7 %). Forty-eight patients out of 307 (15.6%) had GERD symptoms.

Early and Late Morbidity

Early morbidity was 1.6%. Reoperations were necessary in three patients (1.0%). Two patients were revised due to leakage at the proximal staple line, one after pLSG and one after rLSG. One patient underwent reoperation due to kinking of the gastric sleeve. One portal vein thrombosis and one splenic

Table 2 Characteristics and preoperative data on patients undergoing primary laparoscopic sleeve gastrectomy with group 1 (2004–2011) and group 2 (2012–2014). Data are given as mean ± SD. *BMI*, body mass index

	Group 1	Group 2	*p* value
n	138	124	NA
Female (%)	72.5	62.9	0.112
Age (years)	42.0 ± 11.0	45.0 ± 13.6	0.050
Initial weight (kg)	130 ± 24.2	135 ± 29.9	0.136
Initial BMI (kg/m^2)	46.0 ± 7.3	46.8 ± 8.8	0.422
Excess weight (kg)	59.2 ± 20.9	62.7 ± 26.3	0.232
Excess BMI (kg/m^2)	21.0 ± 7.3	21.8 ± 8.8	0.422

infarction occurred and were treated conservatively. In the long-term, complications after pLSG and rLSG were reflux (32.4%, 1.5% combined with hiatal hernia), incisional hernia (4.9%), stenosis (1.3%), and late leak at the staple line (0.3%). Mortality related to LSG was zero; all-cause mortality was 8/307 (2.6%). Causes of death were aortic dissection in one patient, multiorgan failure due to bilateral pneumonia in one patient, suicide after stroke in one patient, malignancy in two patients, and in three patients, the cause remained unknown. The deaths occurred on average 5.8 ± 3.2 years post-surgery.

Weight Loss and BMI Changes

Data on weight loss up to 13 years postoperatively are shown in Fig. 1. %EBMIL tended to be lower in patients undergoing pLSG, compared to rLSG; it reached significance at 6 (p = 0.022) and 9 years (p = 0.048) postoperatively. After 6 years, the %EBMIL was 61.6 ± 25.2% for pLSG and 50.1 ± 22.2% for rLSG. Nine years postoperatively pLSG patients reached a %EBMIL of 57.6 ± 24.5%, whereas rLSG patients had an %EBMIL of 45.4 ± 29.5%. After 10 years, 51.8% of LSG patients had a %EBMIL over 50% (54.4% for pLSG and 46.4% for rLSG), whereas 25.9% had a %EBMIL over 75% (26.3% for pLSG and 25.0% for rLSG). Patients with a %EBMIL over 75% had an initial BMI of 44.0 ± 6.9 kg/m^2 and a mean age at the time of operation of 41.0 ± 11.1 years.

Learning Curve

The two pLSG groups (group 1: 2004–2011; group 2: 2012–2014) did not show a significant difference in terms of weight loss within 7 years of follow-up with a similar rate of %EBMIL (Fig. 2). In group 2, 30.9% of patients had a %EBMIL of more than 75% up to 7 years compared to 27.8% in group 1. A %EBMIL over 50% was found in 69.1% of group 2 patients and 66.7% in patients from group 1.

Comorbidities

All patients had a complete assessment of their comorbidities at the last follow-up. At a mean follow-up time of 7.5 ± 3.4 years postoperatively, remission of comorbidities was 61% for T2DM, 60.5% for hypertension, 54.8% for dyslipidemia, 46% for sleep apnea, 50.3% for arthralgia, and 45.8% for reflux. Additionally, improvement in T2DM was found in 2.6%, in hypertension in 4.2%, in dyslipidemia in 7.8%, in sleep apnea in 7.9%, and in arthralgia in 10.8%. Twenty-five patients (52.1%) with preoperative reflux had persistent or worsened GERD symptoms during follow-up. Of all patients without preoperative reflux, 84/259 (32.4%) developed de novo reflux during follow-up.

Revisions

Revisions were necessary in 59/307 patients (19.2%). Twenty-four patients were reoperated due to insufficient weight loss 24/59 (40.7%), 12/59 because of reflux (20.3%), and 23 due to both (39.0%), either by conversion to Roux-en-Y gastric bypass (n = 35) or biliopancreatic diversion with duodenal switch (n = 24) (Fig. 3). On average, the revisional bariatric procedure was performed 4.2 ± 2.6 years after initial LSG. The reoperation rate was higher in pLSG (14.7%) than that in rLSG (4.6%). Patients from group 1 had conversion in 17.4 % (n = 24) and from group 2 in 16.9 % (n = 21).

Discussion

This study's main finding was the long-lasting weight loss and control of comorbidities in patients who underwent primary or revisional LSG. The primary LSG led to an %EBMIL of 53.6% after 10 years and 51.2% after 13 years in our cohort, comparable to other studies investigating long-term results of LSG [16, 17]. However, bariatric surgeons should be aware of

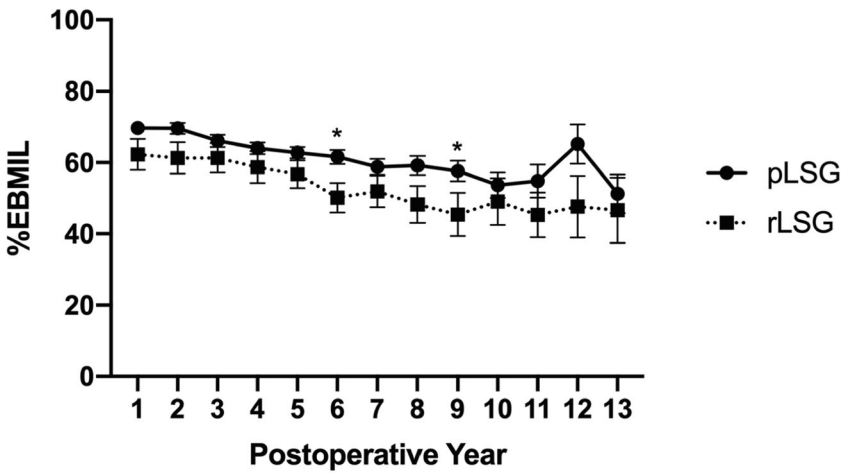

Fig. 1 Postoperative %EBMIL changes over the study period for primary (pLSG) and revisional laparoscopic sleeve gastrectomy (rLSG). Data are presented as mean ± standard error of mean. POY, postoperative year; %EBMIL, percentage excess body mass index loss; %TWL, percentage total weight loss; *p value< 0.05

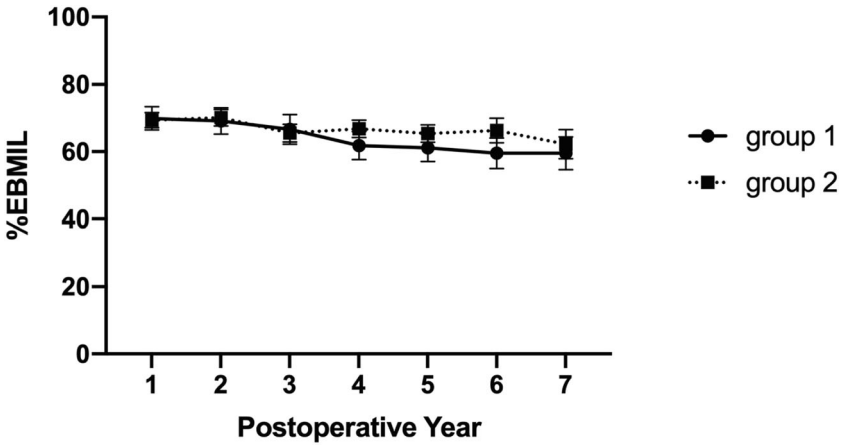

Fig. 2 Postoperative %EBMIL changes for group 1 and group 2 with primary laparoscopic sleeve gastrectomy. Data are presented as mean ± standard error of mean. POY, postoperative year; %EBMIL, percentage excess body mass index loss; %TWL, percentage total weight loss

the high rate of reoperations due to insufficient weight loss, weight regain, or severe GERD.

Ten years postoperatively, over 50% of all patients with LSG showed a %EBMIL > 50%, whereas almost a quarter showed a %EBMIL higher than 75%. The nadir weight loss was observed between the first and second postoperative year with a constant decrease of %EBMIL over the years. Similar results of weight loss over a long-term period were shown by Felsenreich et al. [8] with an excess weight loss (EWL) of 52% in 32 patients after 10 years and Gadiot et al. [18] with 53.9% EWL in 26 patients after 8 years. Better outcomes in terms of weight loss but with smaller study populations were reported by Sarela et al. [19] with an EWL of 68% at 8 to 9 years in 13 patients. Arman et al. [17] reported a mean %EBMIL of 62% after 11 or more years with a relatively poor follow-up (59%). The authors discuss that these high rates of %EBMIL might be due to suboptimal follow-up and a significant selection bias, since some LSG patients may have been candidates for a two-stage surgery but did not get the second operation. All patients included in this study were scheduled for LSG as a definitive procedure, without a planned second step. Enlargement of the gastric sleeve may be one of the leading causes for weight regain over longer periods after the procedure. Felsenreich et al. [9, 16] has reported sleeve enlargement in 57% of the non-converted patients after 10 years. However, a further explanation could be a learning curve. The learning curve is defined as the number of consecutive interventions necessary to reach proficiency in a particular procedure. It may be considered completed when the incidence of postoperative complications and the variation of operative parameters do not exceed the accepted rate [20]. Zacharoulis et al. reported that the learning curve in LSG requires at least 68 cases [14]. In the beginning, we started the resection line at approximately 6 cm proximal of the pylorus. Later on, a larger portion of the antrum was resected. P. Marceau [18] started the sleeve resection in BPD/DS at the level of the angulus because the demand of restriction was less. To improve the weight result of LSG alone, without further need for the second stage procedure, sleeve volume became smaller, and a larger portion of the antrum was resected also by other authors. In a randomized trial published by Abdallah et al. [21], a significantly better weight loss was

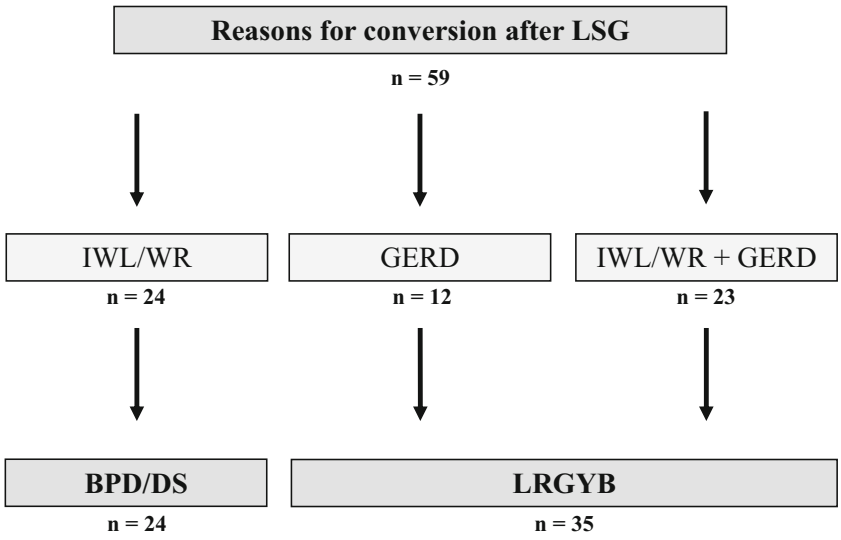

Fig. 3 Reasons for conversion to a secondary bariatric procedure and strategy in case of insufficient weight loss or reflux. LSG, laparoscopic sleeve gastrectomy; IWL, insufficient weight loss; GERD, gastroesophageal reflux disease; BPD/DS, biliopancreatic diversion duodenal/switch; LRYGB, laparoscopic Roux-en-Y gastric bypass

seen in patients with a LSG starting at 2 cm proximal to the pylorus instead of 6 cm. On the other hand, several studies showed that using different bougie diameters did not result in significantly greater weight loss [19, 20]. We could not demonstrate a learning curve regarding weight loss when group 1 was compared to group 2 (Fig. 3).

Long-term studies on comorbidities and their improvement are quite limited. In our cohort, comorbidities improved significantly after LSG. The remission rate was 61% for T2DM, 60.5% for hypertension, 54.8% for dyslipidemia, and 46% for sleep apnea, which is higher compared to other long-term studies [8, 17]. One long-term study with a follow-up of 8 years showed even higher remission rates for both T2DM (74%) and hypertension (77%) [22]. In the STAMPEDE trial, Schauer et al. found that in patients with poorly controlled T2DM at baseline, remission rates following LSG at 3 years were 47%, and at 5 years 36% [2, 23]. These data show that several patients with LSG seem to experience T2DM relapse in the long run, which is in line with our 5-year results from the SM-BOSS trial [7], where 18.1% experienced relapse. In terms of GERD, a short-term improvement of symptoms has been described in some trials, which the authors explained by the decrease of intraabdominal pressure in consequence of weight loss [24, 25]. We found remission of reflux in 45.8% of patients. However, many patients developed de novo reflux (29.8%) or had persistent or worsened GERD symptoms during follow-up (52.1%). Boza et al. [26] found de novo reflux in 26.7% of their cohort after 5 years. Himpens et al. [27] described a rate of new-onset reflux of 21% after 6+ years. A possible reason for new-onset reflux could be caused by weight regain and increased abdominal pressure leading to a hiatal hernia. Barrett's metaplasia has been found as a consequence of chronic reflux. Genco et al. [12] showed newly diagnosed Barrett's metaplasia in 17.2% of their patients with LSG at a mean follow-up time of 4.8 years. Felsenreich et al. [11] found Barrett's metaplasia in 15% at 10 years after LSG. A recently published retrospective analysis of the New York State Database, looking at all adult patients who underwent bariatric surgery from 1995 to 2010, found a higher incidence of GERD and reflux esophagitis in patients with LSG [28]. However, the incidence of esophageal adenocarcinoma did not differ by bariatric surgery type.

In case of insufficient weight loss, weight regain, or severe GERD after LSG, almost a fifth (19.2%) of our study population needed a conversion to a different procedure. In contrast to other long-term studies, our cohort had a lower rate of reoperations [8, 17, 19]. Thirty-five patients were converted to LRYGB due to reflux or both reflux and insufficient weight loss. On the other side, BPD/DS was performed in 24 patients because of insufficient weight loss. Some authors reported that in case of weight regain or insufficient weight loss after LSG, revisional surgery with a long biliopancreatic limb (e.g., BPD/DS, one anastomosis duodeno-ileostomy (SADI-S), long biliopancreatic limb LRYGB, or one anastomosis gastric bypass) should be considered [29, 30].

The present study has some limitations. Besides the retrospective nature of our data, the follow-up rate beyond 10 years was relatively low. About 31.4% of patients were lost to follow-up at 10 years and 39.4% at 13 years, a common problem seen in the bariatric literature.

Conclusions

Patients with LSG experience a long-lasting weight reduction and good control of comorbidities. However, there is a significant reoperation rate in patients with LSG due to insufficient weight loss, weight regain, or severe GERD.

Declarations

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent does not apply as this is a database analysis.

Conflict of Interest MK, VS, TP, MS, and BW declare no competing interests. RS reports grants from the University of Basel, grants from University Hospital Basel, Department of Surgery, grants from SFCS, grants from Gebauer Stiftung, and grants from Freiwillige Akademische Gesellschaft Basel, outside the submitted work. RP reports grants and personal fees from Ethicon Endo-Surgery, outside the submitted work.

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